IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, ***Plaintiff*,** **v.** **ANDREW BAILEY,** in his official capacity as Attorney General of Missouri**; JAMES L. GRAY,** in his official capacity as President of the Missouri Board of Pharmacy; **CHRISTIAN S. TADRUS,** in his official capacity as Vice-President of the Missouri Board of Pharmacy; and **DOUGLAS R. LANG, ANITA K. PARRAN, COLBY GROVE, TAMMY THOMPSON,** and **DARREN HARRIS,** in their official capacities as members of the Missouri Board of Pharmacy**,** ***Defendants*.**	**No. 2:24-cv-04144-MDH**

AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA") brings this Amended Complaint to challenge Missouri Senate Bill No. 751 ("S.B. 751"), codified at Mo. Rev. Stat. § 376.414, and states as follows:

PRELIMINARY STATEMENT

2. The federal 340B Drug Pricing Program, 42 U.S.C. § 256b ("340B"), requires that drug manufacturers whose products are eligible for reimbursement under Medicare Part B and Federal Financial Participation under the Medicaid program must make an "offer" to sell certain drugs at steep price reductions to 15 specified types of eligible healthcare providers ("covered

entities"). 42 U.S.C. § 256b(a)(1), (4). Congress authorized the Secretary of Health and Human Services ("HHS") to enforce and resolve disputes under 340B through a range of carefully balanced federal administrative mechanisms designed to incentivize drug manufacturer participation in each of these programs. *Id.* § 256b(a)(5)(C)-(D), (d). The obligations of drug manufacturers to *offer* 340B pricing are provided by statute and by federal contract—a Pharmaceutical Pricing Agreement ("PPA") between each manufacturer and HHS.

3. Multiple federal Courts of Appeals have now addressed two types of proposed terms that are permissible under federal law in a drug manufacturer's "offer" pursuant to 42 U.S.C.§ 256b(a)(1): (1) "claims data" requirements; and (2) "one contract pharmacy" policies. *See Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460-64 (D.C. Cir. 2024); *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Human Servs.*, 58 F.4th 696, 703-06 (3d Cir. 2023). But Missouri's S.B. 751 impermissibly seeks to render those same terms illegal under state law, and to punish any drug manufacturer that acts consistent with the precise manner approved by those two appellate cases.

340B is a quintessential federal program.

4. At the heart of this litigation is an effort by PhRMA and its member drug manufacturers to protect the integrity of 340B. Congress created 340B to help underserved patient populations who receive treatment at covered entities. But over recent years, the federal program has morphed into a money-making enterprise for national pharmacy chains and others who seek to enrich themselves at the expense of these underserved patients. For-profit pharmacy interests, acting in concert with covered entities and others, improperly leverage 340B pricing for their own financial advantage, often without providing any direct benefits to the vulnerable patient populations 340B was intended to help. Most recently, those who have improperly benefitted from

340B have succeeded in lobbying state legislatures to intervene on their side. These intrusions are not aimed at ensuring patient access to drugs—instead, they directly and intentionally seek to provide 340B pricing in circumstances where federal law does not provide for it.

5. The United States Supreme Court has previously invalidated efforts to distort and undermine the quintessentially *federal* nature of 340B. In *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011), the Court rejected an effort by a group of county medical facilities (covered entities) to enforce 340B drug pricing requirements outside the federal administrative mechanisms provided in the 340B statute. The Supreme Court explained that 340B must be "harmoniously" administered on a "nationwide basis," with HHS "hold[ing] the control rein." *Astra*, 563 U.S. at 120 (stressing the "interdependent nature of [340B and Medicaid]" and explaining that "an adjudication of rights under one program must proceed with an eye towards any implications for the other").

Expressly targeting 340B, S.B. 751 conflicts with and undermines the federal program.

6. This case concerns Missouri's S.B. 751, which targets drug manufacturers in an effort to force them to provide 340B-priced drugs to an *unlimited* number of pharmacies of a covered entity's choosing (so-called "contract pharmacies"). In direct contravention of the Supreme Court's reasoning in *Astra* and the 340B statute, S.B. 751 provides an alternative state law mechanism, on threat of criminal penalty, to compel manufacturers to provide federal 340B price reductions in a manner directly at odds with federal law.

7. S.B. 751 explicitly and repeatedly identifies its target—the federal 340B program, specifically 340B-priced drugs that have "been subject to any *offer* for reduced prices" and are "purchased by a covered entity." S.B. 751, § 1 (emphasis added). And, as Missouri Governor Michael L. Parson recognized in declining to sign S.B. 751 and instead merely allowing it to

become law without his signature: "[T]he 340B program is a product of federal law and regulations. [S.B] 751 inhibits the federal program's structure by placing limitations on how program participation is managed." *See infra* at ¶ 106 (discussing Governor's statement on S.B. 751). The Governor was correct: S.B. 751 is a transparent attempt to regulate drug pricing by imposing federal 340B price reductions where they would not apply under federal law.

8. S.B 751's principal prohibition, in subsection 2, addresses two separate but related activities: restriction of either (a) "the acquisition of a 340B drug by" or (b) the "delivery of a 340B drug to," a pharmacy that is under contract with, or otherwise authorized by, a covered entity to receive 340B drugs. Both elements of this prohibition refer specifically to a 340B-priced drug under federal law. *See* S.B. 751, § 2; *see* also *id.* § 1 (defining "340B drug").

9. Understanding that it cannot legally mandate federal 340B pricing, Missouri and others have now tried to rationalize S.B. 751 as only a drug "delivery" regulation, ignoring the statute's regulation of the "acquisition of a 340B drug."

10. Even focusing solely on S.B. 751's term "delivery," it is undisputable that Missouri pharmacies can already order and receive delivery of the drugs at issue *at market prices*. Thus, the only genuine question under S.B. 751 is whether and when the reduced federal 340B price applies.

11. Under the Supremacy Clause of the United States Constitution, Missouri has no authority to define who is eligible to receive drugs at federally mandated 340B prices. 42 U.S.C. § 256b(a)(1). That is an exclusively federal responsibility.

12. Indeed, were Missouri to attempt to determine which patient prescriptions could qualify for federal 340B pricing, it would also need to determine a host of federal law issues, including: (**a**) whether the particular patient prescription was issued in connection with a patient

visit to a 340B facility and thus was genuinely written for a 340B patient pursuant to federal law; (**b**) whether the federal prohibition on duplicate discounts applies to the particular prescriptions at issue, under 42 U.S.C. § 256b(a)(5)(A); (**c**) whether the federal prohibition on "diversion" applies to the particular prescriptions, under 42 U.S.C. § 256b(a)(5)(B); (**d**) whether or not the covered entity's contractual arrangements with a particular contract pharmacy filling these prescriptions comply with federal law; and (**e**) if a genuine 340B prescription is at issue, whether the manufacturer drug pricing does or does not comply with the federal 340B pricing provisions.

13. Missouri could not enforce its statute as to any specific drug manufacturer without first resolving each of these threshold federal issues. In any enforcement proceeding, a drug manufacturer would likely assert defenses requiring these issues to be addressed, and Missouri would need to adjudicate these questions prescription by prescription and attempt to resolve many questions that are exclusively federal.

14. In short, no matter how Missouri tries to characterize its statute, these issues of federal law are inextricably intertwined and unavoidable. It is not possible for Missouri to enforce S.B. 751 without first resolving issues regulated exclusively by the federal government under 42 U.S.C. § 256b, so Missouri will inevitably be addressing questions of federal law.

S.B. 751 explicitly bars specific 340B policies authorized under federal law.

15. Chief among the federal law issues S.B. 751 attempts to regulate are the contours of the "offer" drug manufacturers are required to make under 340B. While two federal appellate courts interpreting the 340B statute deemed "claims data" and "one contract pharmacy" policies appropriate and permissible, S.B. 751 purports to criminalize these policies. *See Novartis*, 102 F.4th at 463-64; *Sanofi Aventis*, 58 F.4th at 703-06. Both types of federally-authorized policies, as well as S.B. 751's attempt to invalidate them, are summarized below:

16. A manufacturer "claims data" policy generally requires, as a threshold requirement for receiving 340B pricing, that a covered entity agree to provide certain data on the prescriptions it claims are 340B-eligible. *See infra* at ¶ 100. Without that type of data, a manufacturer will have little or no information on what those prescriptions are and cannot often determine whether the particular prescriptions qualify for 340B pricing, or whether the federal statutory bans on duplicate discounting and diversion apply. Importantly, access to claims data regarding those prescriptions is essential to the proper functioning of the federal statute. In order to seek federal resolution of certain disputes with covered entities regarding 340B pricing, a manufacturer must first conduct a federally approved audit of a covered entity. *See* 42 U.S.C. § 256b(a)(5)(C), (d)(3)(B)(iv). And, according to HHS, to receive federal approval to audit, a manufacturer must make a showing that it has "reasonable cause" to conclude that such an audit is necessary. 89 Fed. Reg. at 28,644; 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996). Claims data is utilized to make a "reasonable cause" showing. *See Novartis Pharms. Corp. v. Espinosa*, Nos. 21-cv-1479, 21-cv-1686, 2021 WL 5161783, at *8 (D.D.C. Nov. 5, 2021) (holding that, under federal law, manufacturers are permitted to require certain types of data as a precondition of their "offer" of 340B-priced drugs and that this data allows manufacturer "to better utilize the anti-fraud audit and ADR procedures that Congress established for manufacturers in Section 340B"), *aff'd,* 102 F.4th 452 (D.C. Cir. 2024); *Novartis*, 102 F.4th at 463 (noting that claims data requirement was in line with HRSA's own guidance). The federal statutory structure breaks down if a state bans manufacturer access to that claims data.

17. S.B. 751 purports to punish manufacturer efforts to "deny, restrict, or prohibit either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy." S.B. 751, § 2. But, if a covered entity refuses to comply with a manufacturer claims data policy,

acquisition and delivery of a 340B drug will not occur. To date, multiple states attempting to impose statutory requirements like S.B. 751 have either argued that the state statutes were not intended to apply to these types of claims data policies or acknowledged that principles of federal preemption would apply in this particular claims data context. *See infra* at ¶ 128 n.13. Here, because it purports to ban a claims data requirement integral to the federal program's function, S.B 751 is preempted.

18. The *Novartis* case also addressed manufacturer "one contract pharmacy" policies, explaining that "nobody would say that this policy undermines the bona fides of any 'offer' or increases the contract 'price,'" and that such a restriction "conforms to business practices that governed section 340B sales during much of the program's history." 102 F.4th at 463-64. S.B. 751's text would also appear to ban such policies. S.B. 751, § 2.

Decisions from other cases do not bar the relief sought here.

19. Although the Eighth Circuit has addressed one state statute from Arkansas relating to 340B, that case is the subject of a petition for certiorari pending before the Supreme Court. *Pharm. Rsch. & Mfrs. of Am. v. McClain*, No. 24-118 (U.S.). Similar preemption cases are also pending now in the Fourth and Fifth Circuits. *Pharm. Rsch. & Mfrs. of Am. v. Fitch*, No. 24-60340 (5th Cir.); *Pharm. Rsch. & Mfrs. of Am. v. Murrill*, No. 24-30673 (5th Cir.); *Pharm. Rsch. & Mfrs. of Am. v. Brown*, No. 24-01978 (4th Cir.). And the Eighth Circuit holding in *McClain* should not apply to this case in any event, for at least three reasons.

20. *First,* manufacturer claims data policies—a focal point in this case—were not addressed at all in *McClain*.

21. *Second*, as explained *infra* at ¶ 146 n.14, the *McClain* court specifically conditioned its holding on multiple factual presumptions (regarding "agency" and "title") that, on information

and belief, are not true for many, if not all, Missouri contract pharmacy arrangements. Indeed, the prevailing replenishment model used by contract pharmacies is inconsistent with the *McClain* court's factual assumptions regarding "agency" and "title." *See infra* at ¶¶ 73-77.

22. *Third*, Missouri's S.B. 751's text differs materially from the Arkansas statute at issue in *McClain*, highlighting a distinct way in which S.B. 751 is preempted. Specifically, the federal statute at 42 U.S.C. § 256b(a)(1) explains that the obligation to provide 340B pricing only applies to drugs "purchased by" the covered entity. 42 U.S.C. § 256b(a)(1) (pricing requirement applies to "covered outpatient drugs . . . purchased by a covered entity"). As federal courts have concluded, manufacturer offers to sell 340B-priced drugs can be conditioned on both "claims data" and "one contract pharmacy" manufacturer requirements. *Novartis*, 102 F.4th at 460-64. If a potential buyer will not agree to either requirement in a manufacturer offer, there is no offer and acceptance, and thus no "purchase" of a 340B drug by a covered entity under federal law. *See infra* at ¶ 123. Under those circumstances, the 340B pricing requirement will not apply under federal law. 42 U.S.C. § 256b(a)(1).

23. Although S.B. 751 adopts that same fundamental principle of federal law in its definition of 340B drug, S.B. 751, § 1, Missouri now insists that it can mandate the 340B pricing obligation even when the federal statute does not, *i.e.*, even when there is no covered entity "purchase" under federal law and no obligation to provide 340B pricing. This is a dramatic conflict with federal law.

Relief requested.

24. For these and the additional reasons described below, S.B. 751 is preempted by federal law.

25. S.B. 751 also violates the Constitution's prohibition on state extraterritorial

regulation. It directly regulates wholly out-of-state transactions. Indeed, S.B. 751 contains no provisions limiting its application to Missouri covered entities or pharmacies located in the state of Missouri, or even drug sales occurring in Missouri.

26. PhRMA brings this action to declare unlawful this improper state intrusion into the federal 340B scheme. Specifically, PhRMA seeks a declaratory judgment that S.B. 751 is preempted to the extent it applies to claims data policies (Count I) and is preempted to the extent it applies to one contract pharmacy policies (Count II). Additionally, both to preserve its rights pending possible Supreme Court review of the Eighth Circuit's decision in *McClain* and given the inapplicable factual assertions that undergirded that decision, PhRMA asserts field and broader conflict preemption principles (Count III).

27. Finally, PhRMA seeks a declaratory judgment that S.B. 751 violates the Constitution's prohibition on extraterritorial regulation (Count IV).

28. PhRMA also seeks injunctive relief, enjoining the Missouri Attorney General and the Missouri Board of Pharmacy from enforcing S.B. 751 against PhRMA's members and as to the sale of their drugs.

PARTIES

29. PhRMA has its headquarters and principal place of business at 670 Maine Ave., SW, Suite 1000, Washington, DC 20024. PhRMA, a trade association representing the nation's leading innovative biopharmaceutical research companies, advocates for policies that encourage the discovery and development of important new pharmaceutical products. PhRMA's members, which manufacture and sell pharmaceutical products, participate in the federal 340B program and will thus be forced to supply their drugs at a steeply reduced price to Missouri pharmacies under S.B. 751. Neither the claims asserted nor the relief sought in the Amended Complaint requires the participation of any individual member of PhRMA.

30. Defendant Andrew Bailey is the Attorney General of Missouri, the chief law enforcement officer of the state. S.B. 751 provides that a violation of its provision is an unlawful practice under the Missouri Merchandising Practices Act, S.B. 751, § 3. It authorizes several "action[s]" under that Act, including enforcement actions by the Attorney General. Mo. Rev. Stat. §§ 407.095, 407.100.

31. Defendants James L. Gray, Christian S. Tadrus, Douglas R. Lang, Anita K. Parran, Colby Grove, Tammy Thompson, and Darren Harris are members of the Missouri Board of Pharmacy, which is given authority to "investigate any complaint of a violation of subsection 2 of [S.B. 751] by an individual or entity licensed by the board of pharmacy, and to impose discipline, suspension, or revocation of the license of any such individual or entity." S.B. 751, § 4. The Board is also given authority to "promulgate rules to implement the provisions of subsection 2 of [S.B. 751]. *Id.* § 5.

JURISDICTION AND VENUE

32. PhRMA's causes of action arise under 28 U.S.C. § 1331, 42 U.S.C. § 1983, and the United States Constitution. The Court has jurisdiction under 28 U.S.C. §§ 1331 and 1343(a)(3).

33. The Declaratory Judgment Act provides that, in a case of actual controversy within its jurisdiction, a United States court may declare the rights and other legal relations of any interested party seeking such declaration. 28 U.S.C. § 2201(a).

34. This Court has inherent equitable powers to enjoin the actions of state officials if they contradict the federal Constitution or federal law. *Ex parte Young*, 209 U.S. 123, 159-60 (1908); *accord, e.g.*, *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689 (1949).

35. Venue is proper in this district because this action challenges a Missouri law applicable to the sale of PhRMA's members' drugs in this district, and thus S.B. 751 purports to directly restrict and restrain PhRMA members' conduct in selling and distributing drugs within

this district. 28 U.S.C. § 1391(b)(2).

36. Substantial amounts of PhRMA members' drugs are sold under the 340B program to covered entities in this district. For example, HHS's website reflects that there are over 347 covered entities in Missouri. *See* HRSA, Covered Entity Search Criteria, https://340bopais.hrsa.gov/CoveredEntitySearch/000047924. The same HHS website reflects that those covered entities maintain a substantial number of contract pharmacy arrangements, including with contract pharmacies in this district. Accordingly, S.B. 751 is likely to be enforced against PhRMA members in this district.

37. Venue is also proper in this district because Defendants maintain offices in Jefferson City, Missouri, in this district.

BACKGROUND

A. The History of 340B

38. Congress established 340B in 1992 to restore drug discounts that had been provided voluntarily by manufacturers to a select group of safety-net providers before Congress created the Medicaid Drug Rebate Program ("MDRP") in 1990. Indeed, Congress carefully restricted the list of eligible 340B covered entities to certain enumerated types of entities that "provide direct clinical care to large numbers of uninsured Americans." H.R. Rep. No. 102-384, pt. 2, at 12 (1992) ("House Report").

39. Prior to the enactment of 340B, drug manufacturers had offered discounts on certain outpatient drugs on a voluntary basis to specific, clinical care healthcare providers like covered entities, but not to pharmacies. *See* Nicholas C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision After Two-And-A-Half Decades of Uncertainty*, 22 J. Health Care L. & Pol'y 25, 29-30 (2019) ("Prior to the MDRP, drug manufacturers regularly offered discounts to . . . hospitals and other safety net providers"). However, when Congress created the MDRP in

1990, that law took the manufacturers' previous *voluntary* "large discounts" to safety net providers like covered entities and factored them into the calculation of *required* "best price" for purposes of determining Medicaid rebates. *Id.* The unintended consequence of this pricing "snafu" was that drug manufacturers were disincentivized from continuing to provide the voluntary discounts they had provided to safety net providers prior to the MDRP's creation. *See id.*; *see also* House Report at 9-10.

40. Congress created 340B to address the limited problem created by the MDRP's enactment, specifically to restore the discounts that were previously offered voluntarily by manufacturers. *See* Pub. L. No. 102-585, 106 Stat. 4943, 4962; *see also* House Report at 12. When Congress passed 340B, the legislative history indicates that it intended to restore "discounts to these clinics, programs, and hospitals," *i.e.*, "direct clinical care" entities, which had previously received voluntary discounts. House Report at 12.

41. When it passed the 340B law in 1992, Congress estimated that the program would only include approximately 90 hospitals, 85 family-planning clinics, 120 AIDS-intervention sites, 54 AIDS drug purchasing assistance programs, a network of hemophilia treatment centers with 150 facilities, and 2,225 health centers that qualified to participate. *Id.* at 13. Today, those numbers are astronomically higher.

B. The Operation and Growth of 340B

42. 340B "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities," known as "covered entities," that provide healthcare to certain underserved populations. *Astra*, 563 U.S. at 113.

43. In 2022, 340B-priced purchases reached *$53.7 billion, a $9.8 billion increase from 2021 and a nearly $50 billion increase from 2009*. Adam J. Fein, *The 340B Program Reached $54 Billion in 2022 – Up 22% vs. 2021*, Drug Channels (Sept. 24, 2023),

https://tinyurl.com/2nrux6et ("Fein 2023"). Many of these 340B price reductions are not passed on to the indigent or underserved patients actually receiving the drugs.

44. That same year (2022), the list price value (*i.e.*, based on wholesale acquisition cost) of 340B purchases was $106 billion. *Id.*; *see also* Rory Martin, PhD, *The 340B Drug Discount Program Exceeds $100B in 2022*, IQVIA (Apr. 14, 2023), https://www.iqvia.com/locations/united-states/library/white-papers/the-340b-drug-discount-program-exceeds-uds100b-in-2022. That is equal to "more than 16% of pharmaceutical manufacturers' total gross sales of brand-name drugs at list prices." Fein 2023. If this recent growth trend continues unabated, 340B is estimated to become the "largest federal drug program by 2026 exceeding gross drug purchases through Medicare Part D, Medicare Part B and Medicaid." Berkeley Rsch. Grp., 340B Program at a Glance (2021), https://tinyurl.com/ms2afa2y.

45. 340B is governed by a federal statutory framework, implemented by the HRSA, a federal agency within HHS.

46. Under 340B, participating manufacturers "*shall offer*" to each "covered entity" (as delineated by the federal 340B statute) certain outpatient drugs (also specified by statute) at or below a price (again set by statute) *if* such drugs are offered to any other purchasers, meaning manufacturers must make a genuine offer to covered entities for purchase of 340B-priced drugs. 42 U.S.C. § 256b(a)(1). That requirement does not involve an obligation to offer or to provide 340B-priced drugs to an unlimited number of contract pharmacies.

47. Federal law defines "covered entity" for purposes of 340B to mean an entity that "is one of" 15 types of specifically enumerated categories of healthcare providers, 42 U.S.C. § 256b(a)(4), and that meets other specifically enumerated requirements, including that the entity does not engage in an unlawful transfer of 340B-priced drugs and does not seek or cause a

duplicate discount, *id.* § 256b(a)(5).

48. Federally Qualified Health Centers, children's hospitals, critical access hospitals, sole community hospitals (*i.e.*, hospitals geographically isolated from other hospitals, 42 U.S.C. § 1395ww(d)(5)(D)(iii)), and certain other clinics and hospitals are all specifically defined as "covered entities" eligible to enroll and participate in 340B. 42 U.S.C. § 256b(a)(4); *see also Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 820-22 (D.C. Cir. 2020). Pharmacies are not among the listed covered entities. 42 U.S.C. § 256b(a)(4).

49. Federal law defines the "ceiling price" for purposes of 340B to mean "the maximum price that covered entities may permissibly be required to pay for the drug." *Id.* § 256b(a)(1). The ceiling price is the highest price a manufacturer may charge to 340B covered entities for a covered outpatient drug on 340B-eligible purchases. That ceiling price is deeply reduced compared to the drug's market price. Manufacturers must "offer" their covered outpatient drugs at or below the applicable "ceiling price" to "covered entities," and only "covered entities" may receive this pricing under the express terms of federal law. *See id.*

50. Identifying the specific obligations imposed by 340B's "shall offer" provision on drug manufacturers requires the interpretation of 42 U.S.C. § 256b(a)(1) under federal law. According to courts that have reviewed this question to date, a drug manufacturer's appropriate good faith offer means that the manufacturer must provide some meaningful path for covered entities to obtain these medications at the 340B price. *See id.* § 256b(a)(1); *Novartis*, 102 F.4th at 462-64; *Sanofi*, 58 F.4th at 703. But the statute does not mandate a commitment to offer 340B-priced drugs absent contract pharmacy limitations or provide 340B-priced drugs to an unlimited number of contract pharmacies of a covered entity's choosing. *Novartis*, 102 F.4th at 461 ("The requirement to 'offer' drugs at a certain 'price' does not prohibit distribution conditions, much less

require the offeror to accede to any distribution terms demanded by the offeree."); *see also Sanofi*, 58 F.4th at 703.

51. Indeed, "Congress's use of the singular 'covered entity' in the [statute] suggests that it had in mind one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies." *Sanofi*, 58 F.4th at 704; *see also Novartis*, 102 F.4th at 456 (stating that "Congress *has limited* the section 340B program in three important ways," including by defining "'covered entity' to mean only healthcare providers that fit within narrow categories" (emphasis added)). And "[n]o other language in Section 340B requires delivery to an unlimited number of contract pharmacies." *Sanofi*, 58 F.4th at 704.

52. To the contrary, the 340B statute forbids covered entities from "resell[ing] or otherwise transfer[ring]" a covered outpatient drug "to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B).

53. Congress has not expressly commanded pharmaceutical manufacturers to participate in 340B. *See Astra*, 563 U.S. at 117-18. Instead, participation in 340B is generally understood as a condition for manufacturers' drugs to be eligible for reimbursement under either Medicare Part B or the federal share of Medicaid (in general, programs that provide elderly and financially needy patient populations access to health coverage). 42 U.S.C. § 1396r-8(a)(1), (5); *see also Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 579-80 (2012).

54. Manufacturers "opt into" 340B by signing a form federal contract with HHS "for covered drugs purchased by 340B entities." *Astra*, 563 U.S. at 113. That form contract is known as the PPA. *Id.* at 117. PPAs do not meaningfully vary between manufacturers, but "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them." *Id.* at 118.

55. If HHS determines that a manufacturer breached its 340B obligations, HHS can terminate the PPA and remove the manufacturer from the 340B program. *See* 42 U.S.C. § 1396r-8(b)(4)(B)(v); 61 Fed. Reg. 65,406, 65,412-13 (Dec. 12, 1996). The manufacturer, in turn, may be forced to withdraw from participating in Medicare Part B and Medicaid, and their drugs will no longer be eligible to receive reimbursements under those programs, which would have a profound impact on many vulnerable patient populations and our healthcare system. *See* 42 U.S.C. § 1396r-8(a)(1), (a)(5), (b)(4)(B)(v).

56. Given the stakes for Medicare Part B and Medicaid and their patient populations, Congress chose to assign oversight and enforcement responsibilities exclusively to HHS to ensure the delicate balance that maintains manufacturer participation. HHS, in turn, has delegated 340B's oversight and enforcement to its component agency, HRSA. Neither the 340B statute nor any federal regulations promulgated under it authorize, envision, or create room for state regulation of the 340B program. Indeed, the Supreme Court made that clear in *Astra*, holding that the administration and enforcement provisions established an exclusive system of federal management designed to be "harmoniously" administered on a "nationwide basis," with HHS "hold[ing] the control rein." *Astra*, 563 U.S. at 120.

57. Congress has also carefully specified the exclusive mechanisms available for administering 340B disputes and violations: audits, an enforcement scheme directed by HHS, and a process known as administrative dispute resolution ("ADR"). For instance, the statute specifies that manufacturers have a right to audit covered entities to ensure that the covered entity is complying with the 340B program's requirements. 42 U.S.C. § 256b(a)(5)(C). Manufacturers, in turn, are also subject to compliance audits. *Id.* § 256b(d)(1)(B)(v).

58. Following the Supreme Court's decision in *Astra*, covered entities appeared to

understand that any disputes regarding the entities eligible for 340B-priced drugs, including those centered on contract pharmacy use, presented issues of federal law. Indeed, multiple covered entities filed petitions under the federal 340B statute with the federal agency seeking to resolve those contract pharmacy issues. One group of covered entities alleged that a drug manufacturer "ha[d] violated the 340B statute and regulations by failing to offer covered outpatient drugs at the 340B ceiling price through Petitioner's contract pharmacy arrangements." Those entities asked HHS "to order [the manufacturer] to resume offering covered outpatient drugs at the 340B ceiling price to Petitioner through its contract pharmacies; and to order [the manufacturer] to pay Petitioner an amount equal to the 340B discounts that [the manufacturer] has failed to provide." Another group of covered entities maintained in a 2023 filing that HHS had jurisdiction over its contract pharmacy dispute under the 340B statute because it "has authority to enforce the 340B statute." Petition for Damages and Equitable Relief ¶ 1, *Open Door Cmty. Health Ctrs. v. AstraZeneca Pharms., LP*, ADR ID: 210112-1 (HHS ADR Bd. Jan. 13, 2021), https://pink.citeline.com/-/media/supporting-documents/pink-sheet/2021/01/open-door-adr-petition.pdf?rev=99130335a69d448fafa0110cab3230f6&hash=676DEFD45F067461E1FB3E72CD3CA492; *see also* Petition for Monetary Damages and Equitable Relief ¶¶ 35-37, *Univ. of Wash. Med. Ctr. v. AstraZeneca Pharms. LP* (HHS Bd. Sept. 29, 2023) (Petition by a different group of covered entities asserting panel has jurisdiction over contract pharmacy disputes).

59. Federal regulations issued in 2024 make clear the federal agency's view that it has federal statutory authority to address issues regarding manufacturer contract pharmacy policies, including through the federal statutory "administrative dispute resolution" mechanism. *See* 89 Fed. Reg. 28,643, 28,649 (Apr. 19, 2024) (defining overcharge to encompass "a claim that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or

below the 340B ceiling price or the manufacturer does not offer the 340B ceiling price"). In other words, the federal government believes it has authority to address the same precise subject matter as S.B. 751 purports to regulate. *Id.*; 42 U.S.C. § 256b(d)(1) (covering "overcharges and other violations of the discounted pricing requirements").

60. Similarly, the imposition of penalties for violating 340B is directly committed to the federal government: HRSA evaluates manufacturers' compliance with the 340B statute's requirements and may seek to have HHS impose civil monetary penalties on manufacturers that purposefully charge covered entities more than the statutory 340B ceiling price for covered outpatient drugs.

61. Specifically, HRSA may seek to have HHS impose civil monetary penalties of nearly $6,813 "for each instance of overcharging" a covered entity. Annual Civil Monetary Penalties Inflation Adjustment, 88 Fed. Reg. 69,531, 69,535 (Oct. 06, 2023) (final rule); *see also* 42 U.S.C. § 256b(d)(1)(B)(vi); 42 C.F.R. § 10.11(a). "Overcharging" refers to charging a covered entity a price above the applicable 340B "ceiling price." Congress has specified that these civil monetary penalties can attach to manufacturers only where they "knowingly and intentionally" overcharge. 42 U.S.C. § 256b(d)(1)(B)(vi)(III). Before imposing sanctions, HHS must serve written notice, 42 C.F.R. § 1003.1500(a), and provide advance warnings, *see* 42 U.S.C. § 256b(d)(1)(B)(ii) (requiring HHS to establish procedures to resolve disputes amicably, including through dialogue with the agency).

62. 340B also provides for resolving 340B disputes between manufacturers and covered entities via an ADR process to be established through "[r]egulations promulgated by the Secretary [of HHS]." Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 826-27 (2010) (codified at 42 U.S.C. § 256b(d)(3)) (amending the statute to require

HHS to promulgate regulations establishing ADR).

63. These regulations must "designate or establish a decision-making official or decision-making body within [HHS] to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price . . . and claims by manufacturers that violations of [statutory prohibitions on unlawful transfers of 340B drugs and duplicate discounts] have occurred." *Id.* (codified at 42 U.S.C. § 256b(d)(3)(B)(i)); *see* 42 C.F.R. § 10.20 (setting out requirements for ADR review panels). According to those regulations, claims adjudicated through ADR can include, among others, "[c]laims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug[.]" 42 C.F.R. § 10.21(c)(1); *see also* 89 Fed. Reg. 28,643, 28,657 (Apr. 19, 2024) (amended rule that went into effect on June 18, 2024). As explained below, covered entities have previously taken the position that the ADR process applies to claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B "ceiling price," including through manufacturer "contract pharmacy" policies.

64. HRSA regulations also must be designed with such safeguards and "procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously." 42 U.S.C. § 256b(d)(3)(B)(ii). To ensure finality and repose, the statute provides that "administrative resolution of a claim or claims . . . shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." *Id.* § 256b(d)(3)(C).

65. Covered entities must also comply with additional requirements under 340B. As explained above, covered entities are prohibited from "resell[ing] or otherwise transfer[ring] the drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B) (prohibiting unlawful

transfers). Covered entities are also prohibited from seeking or causing unlawful "duplicate discounts or rebates" from manufacturers. *Id.* § 256b(a)(5)(A). Such "duplicate discounting" most often occurs when a covered entity obtains a drug at the 340B price and dispenses it to a Medicaid patient, and the manufacturer then also pays a Medicaid rebate to the state Medicaid agency on the same drug. A covered entity that engages in unlawful transfers or causes a duplicate discount, both of which would violate § 256b(a)(5), no longer qualifies as a covered entity under the federal statute. *Id.* § 256b(a)(4) (specifying that to qualify as a covered entity, the entity must "meet[] the requirements described in paragraph (5)"). Whether a healthcare entity qualifies as a "covered entity" is a decision entrusted to the federal government.

66. As with manufacturers, covered entities are subject to HHS's enforcement authority. *Id.* § 256b(a)(5)(C)-(D), (d)(2). HHS may impose sanctions, remove a covered entity from the program, and refer matters to other federal authorities where appropriate. *Id.* § 256b(d)(2)(B).

C. Contract Pharmacy Abuses

67. Over the past decade, concerns about abuse in the 340B program have skyrocketed as covered entities have teamed up with contract pharmacies—mostly for-profit pharmacies—nationwide to find ways to maximize the volume of 340B drug price reductions. Under the now prevailing "replenishment model" for stocking and dispensing drugs, contract pharmacies first order drugs at market prices, and then, following sale of those drugs, seek to replenish their inventories with 340B-priced drugs by retroactively identifying, via black-box algorithms, drugs that are purportedly eligible for 340B pricing. As a result and as described above, the volume of drugs purchased at reduced 340B pricing has exploded without any corresponding growth in the patient population.

68. 340B requires that a manufacturer offer 340B pricing only to a "covered entity." 42 U.S.C. § 256b(a)(1). Retail pharmacies are not "covered entit[ies]," so they are ineligible to receive 340B pricing.

69. But certain private, for-profit entities—including the largest national chain pharmacies—have, in increasing numbers, sought to leverage 340B as a tool to enhance their profitability in a way that Congress never intended. This is typically accomplished through complicated contractual arrangements between a covered entity, a pharmacy, and other entities like a third-party administrator. *See Novartis*, 102 F.4th at 457-58.

70. The core feature of these arbitrage arrangements is that the for-profit pharmacies end up obtaining drugs purchased at the 340B price. These contract pharmacies, however, serve not only patients of 340B covered entities, but the general public as well—though 340B-priced drugs are legally permitted to be dispensed only to patients of 340B covered entities. Inevitably, and at great financial benefit to themselves, contract pharmacies sell drugs purchased at 340B prices to patients who are ineligible to receive such 340B-priced drugs.

71. Between 2010 and 2018, the number of such contract pharmacy arrangements with covered entities exploded, increasing "more than fifteen-fold, from about 1,300 to approximately 20,000 [as of 2018]." U.S. Gov't Accountability Off., GAO-18-480, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement 10 (2018) ("2018 GAO Report"), https://www.gao.gov/assets/gao-18-480.pdf. A more recent study put the increase at 4,228%, with now "more than 27,000 individual pharmacies (almost one out of every three pharmacies)" participating in 340B as contract pharmacies. Aaron Vandervelde et al., *For-Profit Pharmacy Participation in the 340B Program*, at 4, Berkeley Rsch. Grp. (Oct. 2020), https://tinyurl.com/3rk5v8nu. By 2020, each covered entity used an average of 22 contract

pharmacies. *Id.* at 7. As a result, the number of actual claims for 340B pricing nationwide *tripled* between 2014 and 2019. *See* Adam J. Fein, *New HRSA Data: 340B Program Reached $29.9 billion in 2019; Now Over 8% of Drug Sales*, Drug Channels (June 9, 2020), https://tinyurl.com/5n7bmw5m.

72. Several federal watchdogs, including the U.S. Government Accountability Office ("GAO") and HHS's own Office of the Inspector General ("OIG"), have warned that the growth of these arrangements exacerbates concerns about abuse and unlawful claims for 340B drugs. *See* 2018 GAO Report at 44 ("The identified noncompliance at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices."); *id.* at 45 ("The expansion of contract pharmacies . . . increases potential risks to the 340B Program, such as risks related to diversion and duplicate discounts.").

73. Here is how the system has evolved over recent years: Under the "replenishment model" now in widespread use by contract pharmacies, the pharmacies sell drugs from their general inventories to all individuals (both 340B covered entity patients and non-340B covered entity patients)—at prices significantly above the 340B price. *See Examining Oversight Reports on the 340B Drug Pricing Program: Hearing Before the S. Comm. On Health, Educ. Labor, & Pensions*, 115th Cong. 11 (2018) (statement of Ann Maxwell, Assistance Inspector Gen. for Evaluation & Inspections, OIG) ("Maxwell Testimony"), https://www.govinfo.gov/content/pkg/CHRG-115shrg30195/pdf/CHRG-115shrg30195.pdf ("[M]any contract pharmacies dispense drugs to all of their customers—340B-eligible *or otherwise*—from their *regular* inventory." (emphasis added)).

74. Then, after subsequent data analysis using undisclosed algorithms, the contract pharmacies purport to retroactively identify individuals with some relationship to a covered

entity—purported covered entity "patients" who were not previously identified as covered entity "patients" at the time the drug was dispensed. *Novartis*, 102 F.4th at 457 (noting that the third-party administrators who run these algorithms "often receive a larger fee for every prescription deemed eligible for the discount").[1] These black-box algorithms likely result in contract pharmacies claiming prescriptions as 340B-eligible where the individual who was dispensed the drug is not a covered entity "patient." *See* HHS Office of Inspector General ("OIG"), Mem. Report: Contract Pharmacy Arrangements in the 340B Program OEI 05-13-00431, at 16 (Feb. 4, 2014), https://bit.ly/3eWKmBQ.[2] This process operates in an "after-the-fact" manner inconsistent with the specific program guidance published by HRSA. Although that guidance provides that each prescription be verified as 340B eligible at the time of drug dispensing, no prescriptions are verified in this manner under the replenishment model. *See* 61 Fed. Reg. 43,549, 43,556 (Aug. 23, 1996); *see Novartis*, 102 F.4th at 457 ("Only after dispensing the drugs do these pharmacies attempt to discern whether individual customers were patients of covered entities—in other words, whether individual prescriptions were eligible for the discount.").[3]

75. Under the replenishment model, after using some undisclosed process to identify

[1] *See, e.g.*, 2018 GAO Report at 2; Maxwell Test. at 11.

[2] HHS OIG has acknowledged this problem. It discussed the following hypothetical: a physician, who practices part-time at a covered entity hospital, gives a prescription to a patient at his private practice. *See* Maxwell Test. at 11. Although this prescription would likely not qualify for 340B, *see* 80 Fed. Reg. 52,300, 52,306 (Aug. 28, 2015), one contract pharmacy said it would claim a 340B price because it simply matches the name of the prescriber with those who work at a 340B covered entity *at all* (even if only part time), *see* Maxwell Test. at 11. This demonstrates how contract pharmacies can expand the definition of an eligible "patient" to cover additional, non-340B prescriptions. *See also Novartis*, 102 F.4th at 458 (remarking on this very issue).

[3] This is one reason why claims for 340B-priced drugs have grown tremendously, while the number of patients treated by covered entities has not. *See* William Smith & Josh Archambault, *340B Drug Discounts: An Increasingly Dysfunctional Federal Program*, at 5, Pioneer Health (Mar. 2022), https://bit.ly/3MShVog.

drugs that may have been sold to purported patients of a covered entity, the pharmacies then purchase additional drugs at the 340B price—nominally in the name of the covered entities—to "replenish" the drugs sold previously to the purported patients. Again, this is done after the fact, without the benefit of data verifying that these newly identified 340B patient prescriptions were actually issued in connection with a patient visit to a covered entity.

76. Once those replenishment drugs are received, the cycle starts anew: the 340B-priced drugs are again commingled in the pharmacy's general inventory and dispensed to any individual who walks in the door, regardless of covered entity patient status. Decl. of Krista M. Pedley ¶ 11, *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, No. 21-cv-00634-PGS-JBD (D.N.J. June 24, 2021), ECF No. 93-2 (HRSA Director of Office of Pharmacy Affairs stating that under the replenishment system, contract pharmacies use stock replenished at 340B prices as "neutral inventory" that "may be dispensed to any subsequent patient").

77. As is evident, the replenishment model simply seeks to lower the price of drugs for pharmacies and covered entities, not patients—by seeking to replenish contract pharmacy inventories with 340B-priced drugs. There is no dispute that the pharmacies could replenish their inventories by ordering the drugs at market prices, but they instead attempt to do so at 340B prices. There is also no dispute that 340B price reductions are not required to be passed along to patients directly.

78. This "replenishment" practice can provide a windfall for covered entities and pharmacies. *See* U.S. Gov't Accountability Off., GAO-20-108, 340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements 5 (2019), https://www.gao.gov/assets/gao-20-108.pdf (explaining that covered entities "purchase [340B-priced] drugs at the 340B Program price for all eligible patients regardless of the patients'

income or insurance status" and "receiv[e] reimbursement from patients' insurance that may exceed the 340B prices paid for the drugs"). As the D.C. Circuit noted, "[t]he covered entity, the pharmacy, and the third-party administrator [who runs the algorithms referenced above] often divvy up the spread between the discounted price and the higher reimbursement rate." *Novartis*, 102 F.4th at 457. Accordingly, "[e]ach of these actors . . . has a financial incentive to catalog as many prescriptions as possible as eligible for the discount." *Id.* at 457-58.

79. By contrast, patients routinely do not receive the benefit of the 340B price reductions in the form of lower prescription costs. *See* Rory Martin & Kepler Illich, *Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?*, at 3, 12, IQVIA (2022), https://tinyurl.com/mvuy8276 (concluding that "most 340B-eligible patients at contract pharmacies are not directly benefiting from 340B discounts" and that stakeholders in the 340B program, such as contract pharmacies, are "profit[ing] from 340B revenue"); Rory Martin & Harish Karne, *The 340B Drug Discount Program Grew to $124B in 2023*, at 6, IQVIA (2024), https://tinyurl.com/y9aeb727 ("If a substantial number of states pass [policies prohibiting the use of contract pharmacy restrictions], it could further accelerate 340B growth in the coming years" and "reignite the problem of duplicate discounts, since it is difficult to determine the 340B status of prescriptions that are filled at contract pharmacies.").

80. Both CVS and Walgreens, two of the largest for-profit pharmacy retailers, have publicly disclosed, for example, that 340B profits are material to their finances. CVS Health Corp., Annual Report (SEC Form 10-K), at 22 (Feb. 8, 2023), https://bit.ly/3Sh3Dl1; Walgreens Boots Alliance, Inc., Annual Report (SEC Form 10-K), at 28 (Oct. 13, 2022), http://bit.ly/3kflVXh ("Changes in pharmaceutical manufacturers' pricing or distribution policies and practices as well as applicable government regulations, including, for example, in connection with the federal 340B

drug pricing program, could also significantly reduce our profitability."). And journalists have revealed how in many cases 340B price reductions are not passed on to vulnerable populations in the form of lower prices.[4]

81. Besides diverting 340B price reductions intended for vulnerable populations into the pockets of for-profit pharmacies, the explosion in contract pharmacy arrangements has also led to an increase in unlawful transfers of drugs purchased at a 340B price. *See, e.g.*, 42 U.S.C. § 256b(a)(5)(B) (prohibiting transfer or sale to anyone "who is not a patient of the [covered] entity"); U.S. Gov't Accountability Off., GAO-11-836, Drug Pricing, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement 28 (2011), https://www.gao.gov/assets/gao-11-836.pdf ("Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."). Indeed, approximately two-thirds of violations for unlawful transfers uncovered by HRSA audits "involved drugs distributed at contract pharmacies." 2018 GAO Report at 44.

82. The use of contract pharmacies can also exacerbate unlawful "duplicate discounting." 42 U.S.C. § 256b(a)(5)(A). Unlawful duplicate discounting forces the manufacturer to provide a price reduction on its drug twice-over—once under 340B to the covered entity, and again in the form of a rebate to the state Medicaid agency.

83. GAO has found that duplicate discounting happens with outsized frequency when covered entities use contract pharmacies. *See, e.g.*, 2018 GAO Report at 45; *see generally* U.S.

[4] *See also* Anna Wilde Matthews et al., *Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients*, WALL ST. J. (Dec. 20, 2022), https://tinyurl.com/bdhhzdhr (explaining that many hospitals do not pass on 340B price reductions to their patients and that 340B appears to bolster profits in well-off areas more than helping hospitals in less-privileged neighborhoods); Katie Thomas & Jessica Silver-Greenberg, *How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, N.Y. TIMES (Sept. 24, 2022), https://tinyurl.com/28ubr4hd (explaining how one hospital "nakedly capitaliz[ed] on" 340B to turn a profit).

Gov't Accountability Off., GAO-20-212, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement (2020), https://www.gao.gov/assets/gao-20-212.pdf. As the GAO explains, this is because of the difficulty of auditing and obtaining reliable data for covered entities with "complex" networks of contract pharmacies. 2018 GAO Report at 45.

D. Covered Entities' Repeated Efforts To Expand 340B

84. Covered entities have repeatedly attempted to circumvent federal authority over 340B to impose their own preferred obligations on 340B manufacturers.

85. In 2006, covered entities filed suit against several pharmaceutical manufacturers, claiming that they had been overcharged for 340B-priced drugs in violation of the PPAs between manufacturers and the federal government. *Astra*, 563 U.S. at 116-17. In 2009, on review, the Supreme Court unanimously rejected such private actions as an alternative 340B enforcement mechanism, emphasizing the need for 340B to be uniformly administered with an eye toward implications for other federal healthcare programs. *Id.* at 120. As the Supreme Court held, "Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities." *Id.* at 117. Rather than allowing "340B entities to launch lawsuits in district courts across the country," with the attendant "risk of conflicting adjudications," "Congress directed HRSA to create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits of manufacturers." *Id.* at 120-21. "Congress thus opted to strengthen and formalize HRSA's enforcement authority, to make the new adjudicative framework *the proper remedy*[.]" *Id.* at 121-22 (emphasis added).

86. Approximately ten years later, with the continued explosion in contract pharmacy arrangements, the increased use of the replenishment model, and documented problems with

program integrity, certain PhRMA members independently adopted new policies to address the 340B abuses reported by federal watchdogs. *See, e.g.*, Second Am. Compl. ¶¶ 44-56, *AstraZeneca Pharms. LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del. July 9, 2021), ECF No. 86 ("AstraZeneca Second Am. Compl.").

87. Although the exact contours of the manufacturer policies differ, they are all intended to curb abuse, and generally, as part of their offer of 340B-priced drugs, provide a limit on the number of outside pharmacies with which a covered entity may contract to receive 340B-priced drugs and require the contract pharmacy to submit data supporting their claims for 340B pricing.

88. Those policies implement reasonable conditions on the provision of 340B-priced drugs where a covered entity has involved one or many contract pharmacies. *See, e.g.*, AstraZeneca Second Am. Compl. ¶¶ 54-56 (permitting covered entities without an in-house pharmacy to designate one contract pharmacy for receipt of 340B-priced drugs); Compl. ¶¶75-78, *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-01686 (D.D.C. June 23, 2021), ECF No. 1; Compl. ¶¶ 41-44, *Novartis Pharms. Corp. v. Espinosa*, No. 1:21-cv-01479 (D.D.C. May 31, 2021), ECF No. 1.

89. In response to such policies, the General Counsel of HHS issued a legal opinion on December 30, 2020, purporting to interpret the 340B statute and declaring that "*to the extent* contract pharmacies are acting as *agents* of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." HHS, Off. of the Sec'y, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program, at 1 (Dec. 30, 2020) ("Advisory Opinion"), https://tinyurl.com/2s4f924r (emphasis added); *AstraZeneca*

Pharms. LP v. Becerra, 543 F. Supp. 3d 47, 55-56 (D. Del. 2021). Although the Advisory Opinion was subsequently vacated on other grounds, it confirms that even HHS concluded that, at a minimum, an agency relationship is required between a covered entity and its contract pharmacy to avoid diversion under the statute, echoing prior HRSA guidance. 61 Fed. Reg. at 43,550, 43,553-55 (HRSA 1996 guidance stating that a covered entity without an in-house pharmacy could contract with *one* contract pharmacy to serve as its "agent").[5]

90. In May 2021, HRSA issued letter decisions to the manufacturers that were implementing policies to address 340B abuses. *See* HRSA, 340B Drug Pricing Program, *HRSA Determines Six Pharmaceutical Manufacturers Are in Violation of the 340B Statute*, Health Res. & Servs. Admin., HRSA Letter to AstraZeneca Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/2nybf4z2 (last visited July 2024); HRSA Letter to Lilly USA, LLC Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/5xkem3y7 (last visited July 2024); HRSA Letter to Novartis Pharmaceuticals Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/jytw6xd6 (last visited July 2024); HRSA Letter to Novo Nordisk Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/ycxwceaz (last visited July 2024); HRSA Letter to Sanofi Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/2veh5838 (last visited July 2024); HRSA Letter to United Therapeutics Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/2p85wz8d (last visited July 2024). Litigation ensued.

[5] Under this 1996 guidance, covered entities were also supposed to "retain[] title" to the drugs, meaning they would "retain[] responsibility." 61 Fed. Reg. at 43,553. That guidance also provides that covered entities are to maintain responsibility "establishing its price." *Id.* at 43,554.

91. In the context of those suits,[6] courts have repeatedly concluded that the scope of manufacturers' obligations does not encompass offering or providing 340B-priced drugs to an unlimited number of contract pharmacies—the exact same requirement Missouri seeks to impose here.

92. The D.C. and Third Circuits specifically began their recent analyses by explaining how the federal statute works and how contract pharmacy and claims data policies interact with it.

93. Both cases involved contract pharmacy and claims data policies. In *Novartis*, one manufacturer was "willing to work with at least one contract pharmacy designated or previously used by the [covered] entity," so long as the "contract pharmacies provide claims data for contract-pharmacy orders." 102 F.4th at 463. The other manufacturer "intend[ed] to deliver section 340B drugs to a covered entity's in-house pharmacy or to a single contract pharmacy designated by the covered entity." *Id.* at 463-64. In *Sanofi*, two manufacturers permitted the use of "one contract pharmacy" if the covered entity "d[id] not have an in-house pharmacy." 58 F.4th at 701. A third manufacturer similarly permitted the use of "one contract pharmacy" if the covered entity "d[id] not have an in-house pharmacy," but also permitted the use of "an unlimited number of contract pharmacies" if the covered entity "agree[d] to provide claims data." *Id.*

94. 340B requires that manufacturers "'offer each covered entity covered outpatient drugs for purchase' at or below a specified ceiling 'price.'" *Novartis*, 102 F.4th at 460 (quoting 42 U.S.C. § 256b(a)(1)). The covered entity who receives such an "offer" can then accept the

[6] *Eli Lilly & Co. v. Becerra*, No. 1:21-cv-81 (S.D. Ind.); *AstraZeneca Pharms. LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del.); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, No. 3:21-cv-00634-FLW-LHG (D.N.J.); *Novo Nordisk Inc. v. U.S. Dep't of Health & Human Servs.*, No. 3:21-cv-00806-FLW-LHG (D.N.J.); *Novartis Pharms. Corp. v. Becerra*, No. 1:21-cv-01479 (D.D.C.); *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-1686-DLF (D.D.C.); *cf. Pharm. Rsch. & Mfrs. of Am. v. Becerra*, No. 21-cv-00198-PWG (D. Md.).

terms of the offer and "purchase" the covered outpatient drugs, or they can decide to not "assent to the same terms" and thus reject the 340B offer. *Id.* (quoting 1 *Corbin on Contracts* § 1.11 (2023)); *see also Sanofi*, 58 F.4th at 703 (holding that manufacturers are required to only "present the drugs [with conditions permitted] for covered entities' acceptance"). Indeed, that Congressional mandate does not "require the offeror to accede to any distribution terms demanded by the offeree." *Novartis*, 102 F.4th at 461; *Sanofi*, 58 F.4th at 703 (holding that the word "offer" does not "imply that the offeror must deliver good wherever and to whomever the buyer demands"). Where a covered entity rejects the offer, the manufacturer has fulfilled its 340B duty and there is no 340B purchase to which the 340B ceiling price applies. *See Novartis*, 102 F.4th at 460; *Sanofi*, 58 F.4th at 703-04.

95. The D.C. Circuit rejected the assertion that 340B requires manufacturers to provide 340B-priced drugs to an unlimited number of contract pharmacies. *Novartis*, 102 F.4th at 460. As the D.C. Circuit concluded, Congress chose to impose only certain restrictions on 340B-participating manufacturers—that they make a "bona fide" offer, *i.e.*, that they "propose to sell covered drugs to covered entities at or below a specified monetary amount." *Id.* This means that manufacturers remain free to impose "conditions on the distribution of covered drugs to covered entities." *Id.* at 459-60.

96. And the D.C. Circuit similarly rejected the notion that purported silence allowed for imposition of an unlimited contract pharmacy requirement. As that court noted, purported "silen[ce] about delivery conditions . . . preserves—rather than abrogates—the ability of sellers to impose at least some delivery conditions." *Id.* at 460-61. The court also noted that this silence did not mean that manufacturers have carte blanche as to conditions. *Id.* at 462-63. Instead, Congress carefully circumscribed the obligations it placed on manufacturers, only permitting conditions that

would not move offers out of the realm of "bona fide" offers. *Id.* The court expressly left to the federal government adjudication of "more onerous conditions" on offers than the ones before it and as-applied challenges to the manufacturer conditions, reviewed by federal courts. *Id.* at 464.

97. The Third Circuit's decision in *Sanofi* likewise rejected the very same obligation Missouri seeks to impose here. 58 F.4th at 703-04. The Third Circuit noted that "Congress's use of the singular 'covered entity' in the [statute's] 'purchased by' language suggests that it had in mind one-to-one transactions between a covered entity and a drug maker *without mixing in a plethora of pharmacies*." *Id.* (emphasis added); *id.* at 704 (340B does not "require[] delivery to an unlimited number of contract pharmacies"). The Third Circuit also expressly enjoined the federal government from imposing this requirement. *Id.* at 706 (barring the federal government "from enforcing against [plaintiffs] its reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies"); *id.* at 704 (noting that "'Congress knew how to' grant covered entities permission to contract with third parties for distribution . . . but did not" (quoting *State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 580 U.S. 36, 39 (2016))).

98. In doing so, the Third Circuit concluded that, despite the statute's "silence" as to the number of permitted contract pharmacies, such an unlimited contract pharmacy requirement "overstepped the statute's bounds," as reflected in 340B's structure and other considerations. *Sanofi*, 58 F.4th at 707. The Third Circuit left open the possibility, however, that the federal obligation may require that manufacturers offer to deliver 340B-priced drugs to some pharmacies in certain circumstances (for example, a single contract pharmacy where a covered entity lacks its own in-house pharmacy). 42 U.S.C. § 256b(a)(1); *Sanofi*, 58 F.4th at 703-04. Thus, *Sanofi* ultimately recognizes there is no gap in 340B—instead the question requires interpretation of federal law. *Id.* at 705.

99. Two other courts are in accord. The U.S. District Court for the District of Columbia, in a subsequently affirmed decision, likewise found that the 340B statute permits drug manufacturers to impose reasonable conditions regarding contract pharmacies as part of the manufacturers' participation in 340B, including a reasonable limitation on where manufacturers will send 340B-priced drugs. *Novartis*, 2021 WL 5161783, at *7. In a similar vein, the U.S. District Court for the District of Delaware found that Congress chose not to require manufacturers to provide 340B-priced drugs to an unlimited number of contract pharmacies. *AstraZeneca*, 543 F. Supp. 3d at 58-59.[7]

100. The same is true of manufacturers' conditions on their offers of 340B-priced drugs that require covered entities and contract pharmacies to provide certain claims data related to the prescriptions that were purportedly dispensed as 340B drugs. Multiple courts have concluded that manufacturers may impose such conditions, and that those conditions on a 340B offer satisfy the federal obligation. *See Novartis*, 2021 WL 5161783, at *8 (holding that, under federal law, manufacturers are permitted to require certain types of data as a precondition of their "offer" of 340B-priced drugs); *id.* ("For its part, [plaintiff manufacturer] convincingly argues that the claims data conditions that it has added to its new 340B policy will enable it to better utilize the anti-fraud audit and ADR procedures that Congress established for manufacturers in Section 340B."); *Novartis*, 102 F.4th at 463 (affirming holding). That leaves covered entities free to accept such offers, along with their terms, or reject them.

101. For their part, covered entities have sought to use the federal ADR mechanism, which is overseen by a panel within HHS, to enforce a purported obligation to provide 340B-priced drugs to any and all contract pharmacies identified by a covered entity. In those proceedings, a

[7] One appeal remains pending. *See Eli Lilly & Co. v. Becerra*, Nos. 21-3128, 21-3405 (7th Cir.).

group of covered entities alleged that a drug manufacturer "ha[d] violated the 340B statute and regulations by failing to offer covered outpatient drugs at the 340B ceiling price through Petitioner's contract pharmacy arrangements." Those entities asked the panel "to order [the manufacturer] to resume offering covered outpatient drugs at the 340B ceiling price to Petitioner through its contract pharmacies; and to order [the manufacturer] to pay Petitioner an amount equal to the 340B discounts that [the manufacturer] has failed to provide." Petition for Damages and Equitable Relief ¶ 1, *Open Door Cmty. Health Ctrs. v. AstraZeneca Pharms., LP*, ADR ID: 210112-1 (HHS ADR Bd. Jan. 13, 2021), https://pink.citeline.com/-/media/supporting-documents/pink-sheet/2021/01/open-door-adr-petition.pdf?rev=99130335a69d448fafa0110cab3230f6&hash=676DEFD45F067461E1FB3E72CD3CA492; *see also* Petition for Monetary Damages and Equitable Relief ¶¶ 35-37, *Univ. of Wash. Med. Ctr. v. AstraZeneca Pharms. LP* (HHS Bd. Sept. 29, 2023) (Petition by a different group of covered entities asserting panel has jurisdiction over contract pharmacy disputes).

102. Dissatisfied with the outcomes in federal court and before the federal agency, covered entities turned their sights to lobbying states, seeking to impose on manufacturers, as a matter of state law, a pricing obligation in a federal program that federal courts have already concluded does not exist and cannot be imposed even by the federal agency tasked with 340B's administration and enforcement. While covered entities previously considered contract pharmacy use an issue of pricing, when moving to the states, they now portray such laws as imposing a mere "delivery" obligation on drug manufacturers. But that obligation in S.B. 751 runs directly counter to federal law and also expressly imposes a pricing requirement on drug manufacturers.

103. The recently enacted Inflation Reduction Act ("IRA") also makes clear the interrelationship between 340B and Medicare, and highlights once again the quintessentially

federal nature of the 340B pricing regime.[8] The IRA establishes the Medicare Drug Price Negotiation Program, under which HHS is to "negotiate" with manufacturers "maximum fair price[s]" for certain drugs. 42 U.S.C. § 1320f-3(a). Manufacturers must provide drugs under these so-called maximum fair prices, except when drugs are 340B eligible and the 340B price is lower than the maximum fair price. *Id.* § 1320f-2(d). That is, manufacturers need not provide duplicate 340B and "maximum fair price" discounts. *Id.* To avoid duplicate discounting, this scheme necessarily requires identifying when a drug subject to the maximum fair price is dispensed as a 340B drug—further demonstrating the "interdependent nature" of Medicare and the 340B program. *Astra*, 563 U.S. at 120.

104. The Centers for Medicare and Medicaid Services ("CMS") has issued final IRA guidance for avoiding duplicate discounting under the Medicare Drug Price Negotiation Program. Under that guidance, a manufacturer bears the burden of determining and verifying whether a "claim for a selected drug is a 340B-eligible claim." CMS, Medicare Drug Pricing Negotiation Final Guidance ("Final Guidance"), at 60;[9] *see also* CMS, Medicare Drug Price Negotiation Program Draft Guidance ("Draft Guidance"), at 48 (A manufacturer must "indicate[] that the claim for [a] selected drug is a 340B-eligible claim and the 340B ceiling price is lower than the [maximum fair price] for the selected drug.").[10] To facilitate the identification of 340B drugs, dispensing entities are encouraged to use claims codes indicating which drugs are dispensed under

[8] Several of PhRMA's members have drugs that are subject to the IRA's Medicare Drug Price Negotiation Program, including Boehringer Ingelheim Pharmaceuticals, Bristol Myers Squibb Company, Astellas, and Merck.

[9] https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

[10] https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

the 340B program, and to provide prescriber identification information to help manufacturers identify "whether a prescription was written by a prescriber with a high percentage of claims originating from a 340B covered entity." Draft Guidance at 41; Final Guidance at 45, 57. Commenters noted "that, under the nonduplication approach described by CMS in the draft guidance, [IRA] Manufacturers would likely mandate 340B claims data submission from covered entities." Final Guidance at 57. "Many commenters strongly opposed CMS allowing for such mandates and stated that, at minimum, CMS should evaluate and regulate the data requirements imposed by [IRA] Manufacturers on covered entities." *Id.* In response to such comments, CMS stated it "will not prescribe a specific nonduplication approach that [IRA] Manufacturers must follow or impose parameters" on it, and noted in its justification that manufacturers bear the burden for ensuring nonduplication. *Id.* at 57-58.

E. Missouri Enacts S.B. 751 To Impose State-Law Conditions On 340B

1. S.B. 751's Passage and Requirements

105. On May 30, 2024, the Missouri legislature delivered S.B. 751 to the Governor for signing.

106. On July 11, 2024, Governor Parsons chose not to sign or veto S.B. 751, and the law is set to become effective on August 28, 2024. Governor Parsons explained his reasoning in an accompanying letter, beginning with his "concern[] about the impact of the 340B program expansion facilitated through [S.B. 751]."[11] Recognizing the concerns raised by Missouri's foray into this federal area, Governor Parsons highlighted that "the 340B program is a product of federal law and regulations," and that S.B. 751 "inhibits the federal program's structure by placing

[11] Gov. Michael L Parson, Letter to the Secretary of State of Missouri (July 11, 2024), https://content.govdelivery.com/attachments/MOGOV/2024/07/11/file_attachments/2934538/SB%20751%20NR.pdf.

limitations on how program participation is managed." *Id.* Further, Governor Parsons noted that "[t]he use of contract pharmacies by covered entities under the program—among other programmatic concerns—is an issue that should be addressed by Congress." *Id.*

107. Governor Parsons also recognized the flaws with S.B. 751's effects. As the Governor recognized, "cost savings" under 340B for covered entities do not have "to be passed onto patients" and there is a "lack[] [of] transparency as to how costs savings are used." *Id.* S.B. 751 "fails to address those concerns, but places strict restrictions on pharmaceutical manufacturers' ability to deny, restrict, or prohibit the acquisition of 340B-priced drugs by pharmacies that are contracted with or authorized by covered entities under the program." *Id.*

108. S.B. 751 expressly provides that its regulatory object is the federal 340B program and 340B-priced drugs. S.B. 751, § 1(1) (defining "340B drug" to be a drug that "[i]s a covered outpatient drug within the meaning of Section 340B of the Public Health Service Act").

109. S.B. 751 also purports to adopt the federal requirement that a covered entity "purchase[]" a 340B drug for the 340B pricing requirement to apply. *Id.* § 1(1)(b)-(c) (providing it applies where a drug "[h]as been subject to any offer for reduced prices by a manufacturer under 42 U.S.C. Section 256b(a)(1)," and "[i]s purchased by a covered entity").

110. S.B. 751 instructs that "[a] pharmaceutical manufacturer . . . or an agent or affiliate of such pharmaceutical manufacturer . . . shall not deny, restrict, or prohibit, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with, or otherwise authorized by, a covered entity to receive 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services." *Id.* § 2.

111. S.B. 751 imposes that requirement without recognition that, in instances where

covered entities do not accept the "offer" made by manufacturers that contain reasonable conditions related to contract pharmacies and claims data, there is no 340B "purchase" and so the 340B pricing requirement does not apply.

112. S.B. 751 defines "pharmacy" in reference to Missouri Chapter 338, which requires licensing of all entities undertaking the practice of pharmacy. *See id.* § 1(5). The Board of Pharmacy, via regulation, has provided that "[n]onresident pharmacies shall not ship, mail, or deliver prescription drugs into Missouri without first obtaining a pharmacy license from the Missouri Board of Pharmacy." Mo. Code Regs. tit. 20, § 2220-2.025.

2. Enforcement

113. S.B. 751 does not acknowledge HRSA's enforcement authority or the congressionally mandated safeguards for administrative dispute resolution under 340B. It also does not consider the limitations on enforcement power Congress deemed necessary to maintain the 340B program's delicate balance.

114. S.B. 751 makes a violation of its substantive provisions an unlawful practice under Missouri's Merchandising Practices Act and authorized "any action" permitted in certain subsections of that act, Mo. Rev. Stat. "§§ 407.010 to 407.130." S.B. 751, § 3. S.B. 751 further provides that "[e]ach package of 340B drugs determined to be subject to a prohibited act under subsection 2 of [S.B. 751] . . . constitute[s] a separate violation under subsection 2." *Id.* "Package" is defined as "the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product." *Id.* § 1(3) (referring to 21 U.S.C. § 360eee(11)(A)).

115. Under the Merchandising Practices Act provisions cited, the Attorney General can seek injunctions and seek civil monetary penalties of up to $5,000 per violation against "[a]ny

person who violates the terms of an injunction, an order to make restitution, or any other judgment or order issued under section 407.100." Mo. Rev. Stat. §§ 407.095, 407.100, 407.110. The Attorney General may also unilaterally issue temporary injunctions of up to 10 days in length, the violation of which is a class E felony. *Id.* § 407.095.

116. S.B. 751 also authorizes the Missouri Board of Pharmacy "to investigate any complaint of a violation of subsection 2 of [S.B. 751] by an individual or entity licensed by the board of pharmacy, and to impose discipline, suspension, or revocation of the license of any such individual or entity." S.B. 751, § 4; *see also* Mo. Code Regs. tit. 20, § 2220-5.050 (requiring licensing or registration of out of state manufacturers). It also gives the Board the authority to "promulgate rules to implement the provisions of subsection 2 of" S.B. 751. S.B. 751, § 5.

117. S.B. 751 expressly rests its purported addition of a state law obligation on the existence of a preexisting federal obligation. *Id.* § 1(1).

118. As a result, in any state enforcement proceeding, a state adjudicator will be required to answer multiple questions of federal law to determine if a manufacturer violated S.B. 751. These include, among other things, whether under *federal* law: (1) a particular covered entity has permissibly contracted with a contract pharmacy under federal law and has the necessary "principal-agent" relationship required to even arguably comply with federal law, 42 U.S.C. § 256b(a)(5)(A)-(B); (2) the covered entity continues to "hold title" to the 340B-priced drugs throughout all relevant transactions (which does not occur under the prevailing "replenishment model"); (3) all of the individuals receiving 340B-priced drugs meet the federal definition of a 340B patient; (4) the particular prescriptions at issue qualify for 340B prices; and (5) the 340B price reductions are duplicative of Medicaid rebates applicable to the same prescriptions, *id.* § 256b(a)(5)(A). For example, a covered entity that sells or transfers 340B-priced drugs to anyone

other than its patients is no longer eligible to receive 340B-priced drugs. *Id.* § 256b(a)(5). Similarly, covered entities violating prohibitions on duplicate discounts are ineligible to receive any 340B-priced drugs. *Id.* § 256b(a)(4)-(5). A Missouri state adjudicator will be required to make these determinations to adjudicate any purported violation of S.B. 751.

CLAIMS FOR RELIEF

CLAIM I

(Declaratory/Injunctive Relief—Preemption Under the Supremacy Clause of the U.S. Constitution – Claims Data Policies)

119. PhRMA re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

120. Federal law is "the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Conflict preemption arises where "the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372-73 (2000); *see Forest Park II v. Hadley*, 336 F.3d 724, 733 (8th Cir. 2003).

121. S.B. 751's restrictions, which limit manufacturers' ability to collect claims data, are conflict preempted.

122. S.B. 751's restrictions disregard and conflict with careful limitations in the federal regime. 340B requires only that manufacturers "offer" 340B-priced drugs to covered entities (*i.e.*, that they provide some meaningful path for covered entities to access these medications). *See* 42 U.S.C. § 256b(a)(1). Multiple courts have concluded that manufacturers may impose reasonable conditions on their offers of 340B-priced drugs that require covered entities and contract pharmacies to provide certain claims data related to prescriptions that were purportedly dispensed as 340B drugs. *See Novartis*, 2021 WL 5161783, at *8 (holding that, under federal law, manufacturers are permitted to require certain types of data as a precondition of their "offer" of

340B-priced drugs); *id.* ("For its part, [the plaintiff manufacturer] convincingly argues that the claims data conditions that it has added to its new 340B policy will enable it to better utilize the anti-fraud audit and ADR procedures that Congress established for manufacturers in Section 340B."); *Novartis*, 102 F.4th at 463-64 (affirming holding).

123. That is reinforced by the regime that Missouri has adopted here. The federal statute explains that the obligation to provide 340B pricing applies only to covered outpatient drugs "purchased by" the covered entity. 42 U.S.C. § 256b(a)(1) (specifying that ceiling price applies to "covered outpatient drugs . . . purchased by a covered entity"). As federal courts have concluded, manufacturer offers to sell 340B-priced drugs can be conditioned on both "claims data" and "one contract pharmacy" manufacturer requirements. *Novartis*, 102 F.4th at 463-64. If a potential buyer will not agree to a manufacturer claims data requirement in the offer, there is no offer and acceptance, and thus no "purchase" of a 340B drug by a covered entity under federal law. As a result, the 340B pricing requirement will not apply under federal law. 42 U.S.C. § 256b(a)(1).

124. S.B. 751 adopts that same fundamental principle of federal law in its definition of 340B drug. *See* S.B. 751, § 1(1) (defining "340B drug" to be a drug that "[i]s a covered outpatient drug within the meaning of Section 340B of the Public Health Service Act," "[h]as been subject to any offer for reduced prices by a manufacturer under 42 U.S.C. Section 256b(a)(1)," and "[i]s *purchased by a covered entity*" (emphasis added)). But Missouri now insists that it can mandate the 340B pricing obligation even when the federal statute does not, *i.e.*, even when there is no covered entity "purchase" under federal law and no obligation to provide 340B pricing. This is a dramatic conflict with federal law, and another specific reason why S.B. 751 is conflict preempted.

125. In the alternative, this Court should issue a declaratory judgment because on its

face, S.B. 751 can have no effect as to manufacturers' offers with federally permitted restrictions on claims data collection unless Missouri is engaged in an expansion of the federal benefit, which would be conflict preempted.

126. S.B. 751's restrictions also impermissibly limit manufacturers' ability to utilize the federal enforcement scheme. To use the federal administrative dispute resolution mechanism, manufacturers must first audit a covered entity. *See* 42 U.S.C. § 256b(a)(5)(C), (d)(3)(B)(iv); 89 Fed. Reg. at 28,644, 28,649. However, manufacturers are only permitted to conduct an audit where they "ha[ve] documentation which indicates there is reasonable cause." 61 Fed. Reg. at 65,409. "Reasonable cause" is defined to mean "that a reasonable person could believe that a covered entity may have violated" the prohibition on transfer or sale, or the prohibition on duplicate discounting. *Id.* Accordingly, to even access the audit process to engage in an ADR proceeding, manufacturers must be able to access claims data information from covered entities that will allow them to determine if reasonable cause exists to suspect a covered entity is violating 340B's provisions. By purporting to outlaw the collection of claims data as a prerequisite to 340B pricing, S.B. 751 keeps manufacturers from being able to meaningfully utilize the federal resolution process that Congress provided. The Eighth Circuit's decision in *McClain* does not address manufacturer claims data requirements.

127. Additionally, S.B. 751's restrictions will contribute to duplicate discounts and diversion of 340B drugs to ineligible recipients. S.B. 751 conflicts with the federal Medicare Drug Price Negotiation Program by frustrating the disclosure of claims data that is necessary to prevent duplicate discounting with the "maximum fair prices" established under the Inflation Reduction Act. *See* 42 U.S.C. § 1396r-8(a)(5)(C); *see supra* at ¶¶ 103-04.

128. For all of those reasons, S.B. 751's restrictions on claims data conditions are

preempted, and their enforcement should be enjoined.[12]

CLAIM II
(Declaratory/Injunctive Relief—Preemption Under the Supremacy Clause of the U.S. Constitution and the Federal 340B Statute – Contract Pharmacy Policies)

129. PhRMA re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

130. S.B. 751's contract pharmacy provisions are preempted because they directly conflict with the federal statute's terms and the balance struck by Congress.

131. As discussed, *see supra* at ¶¶ 49-50, Congress imposes a requirement to "offer" 340B-priced drugs on manufacturers. As part of that federal offer, manufacturers may include limitations on the use of contract pharmacies. The 340B pricing obligation attaches only where covered entities accept the terms of the offer. *See supra* at ¶ 123.

132. By mandating that manufacturers provide those 340B-priced drugs to any and all contract pharmacies that a covered entity chooses to contract with, the Missouri statute dramatically expands manufacturers' obligations under the federal program and directly conflicts with the scope of those obligations as determined by multiple federal courts. And it seemingly requires manufacturers to do so even where covered entities do not, as required by federal law, retain title to the drugs or have the requisite principal-agent relationship with contract pharmacies. Indeed, Missouri is now seeking to impose as a matter of state law what even the federal

[12] Other states have recognized the conflict presented and contended that their statutes should not be construed to cover claims data policies. *See* Appellee Br. for Mississippi Att'y Gen. at 44, *PhRMA v. Fitch*, No. 24-60340, ECF No. 40 (5th Cir. Nov. 8, 2024) (recognizing that 340B "entitles drug makers to claims data" and stating state statute "honors that entitlement"); Opp'n Br. for Maryland Att'y Gen. at 31, *PhRMA v. Brown*, No. 1:24-cv-01631, ECF No. 19-1 (D. Md. July 2, 2024) (state law would not "preclude manufacturers from obtaining any data or information they are permitted to obtain from covered entities and pharmacies under the 340B program"); *PhRMA v. Fitch*, No. 1:24-cv-160, 2024 WL 3277365, at *10 (S.D. Miss. July 1, 2024) (construing state law as to claims data restrictions so as to not conflict with 340B).

government has been enjoined from requiring of manufacturers under federal law, in connection with an exclusively federal program. *Sanofi*, 58 F.4th at 706; *see also Novartis*, 102 F.4th at 464. As courts have recognized, this expansion of obligations under a federal incentive program is preempted. *Forest Park II*, 336 F.3d at 732-33 (holding states may not impose additional obligations on participants in incentive-based, federal programs, even where the federal statute does not explicitly bar such additional obligations).

133. Nor can S.B. 751 be saved by recasting it as a distribution requirement. Missouri is attempting to regulate who can receive 340B-priced drugs, not drugs in general. No one suggests that manufacturers will not provide those drugs at market prices to pharmacies. The aim instead is to force manufacturers to provide those same drugs to those same pharmacies at a lower price. Indeed, absent the pricing requirement, Missouri's law would be meaningless given that manufacturers already provide the same drugs at market-based prices. S.B. 751, § 1(1) (defining "340B drug" in reference to the federal statutory price).

134. Further, as explained above, Missouri has explained that it can mandate that 340B pricing extend to contract pharmacies even when the covered entity has not "purchased" a covered drug under federal law and a manufacturer therefore has no federal obligation to provide 340B pricing. *See supra* at ¶ 124. The Eighth Circuit in *McClain* did not address this issue. This stark expansion of the federal requirement is clearly conflict preempted.

135. For reasons outlined above, *see supra* at ¶¶ 129-34, S.B. 751 is either conflict preempted or, in the alternative, this Court should issue a declaratory judgment because on its face, S.B. 751 can have no effect as to manufacturers' offers with federally permitted restrictions on contract pharmacy restrictions unless Missouri is engaged in an expansion of the federal benefit, which would be conflict preempted.

136. S.B. 751's state-law enforcement provision also both conflicts with the carefully calibrated system created by Congress to ensure 340B compliance and raises the specter of inconsistent adjudications. Among other reasons, S.B. 751 conflicts because it skews Congress's carefully balanced enforcement scheme by wresting exclusive enforcement authority from HHS and imposing additional state law penalties, including potential criminal penalties where a temporary injunction is violated. And it raises the specter of inconsistent adjudications identified in *Astra* because Missouri cannot pursue enforcement under S.B. 751 without adjudicating multiple questions of federal law, such as determining whether an entity is "authorized to participate in the federal 340B drug discount program"—an issue determined exclusively under the federal 340B statute.

CLAIM III
(Declaratory/Injunctive Relief—Preemption Under the Supremacy Clause of the U.S. Constitution and the Federal 340B Statute – Preemption Generally)

137. PhRMA re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

138. S.B. 751 is both field and conflict preempted. Field preemption exists where (1) Congress's "framework of regulation [is] 'so pervasive'" that Congress has "left no room for the States to supplement it," or (2) where there is a "federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Arizona v. United States*, 567 U.S. 387, 399 (2012) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

139. Field preemption is especially likely where a state law "'diminish[es] the [Federal Government]'s control over enforcement' and 'detract[s] from the integrated scheme of regulation' created by Congress." *Id.* at 402 (quoting *Wisc. Dep't of Indus. v. Gould Inc.*, 475 U.S. 282, 288-89 (1986)).

140. As the Supreme Court has recognized, Congress created a comprehensive federal program in 340B and centralized control of that program exclusively within HHS to safeguard the delicate balance Congress struck. *See Astra*, 563 U.S. at 120 (noting the "interdependent" nature of 340B with other federal programs). No room exists for state supplantation in this field. Congress created the exclusively federal field here through enactment of 340B. Unlike some other federal healthcare programs, where Congress has assigned the states significant roles in administering those programs, it chose not to do so here. *See, e.g.*, 42 U.S.C. § 1396a (Medicaid statute providing for state plans); 42 U.S.C. § 18031 (Affordable Care Act establishing states' ability to set up health benefit plan exchanges).

141. The system crafted by Congress did not impose open-ended obligations on manufacturers. Instead, Congress designed a pervasive and integrated scheme of regulation through creation of a closed and limited system. Congress carefully defined those eligible to receive 340B drugs (enumerated covered entities), set the nature of the benefit (a set ceiling price calculation), and imposed limitations on that benefit (to whom covered entities may furnish 340B-priced drugs). Congress spoke in exacting detail because 340B, given its interconnection with other federal programs, must maintain a delicate balance to ensure that the program achieves its purpose without becoming too onerous for manufacturers, reinforcing that this is an area of dominant federal concern. Finally, Congress set out an exclusive federal enforcement scheme to maintain the program as a harmonious whole.

142. S.B. 751 nevertheless seeks to directly intrude on this carefully balanced federal program by expanding the scope of manufacturers' obligations to include offering and providing 340B-priced drugs to covered entities using an unlimited number of contract pharmacies, and by implementing its own competing enforcement regime. *See* S.B. 751, §§ 1(1), 2. That is far more

than 340B requires, permits, or contemplates. *Sanofi*, 58 F.4th at 703; *see also id.* at 706 (Third Circuit enjoining the federal government from mandating what Missouri is now attempting to do).

143. That intrusion into the field of the operation of 340B is made clear by S.B. 751's scope. Missouri pharmacies can freely order any drug legally available to them at market pricing. S.B. 751 does not seek to expand access to drugs generally—it merely seeks to compel 340B pricing for drug orders. 340B's reticulated scheme regarding manufacturers' "offer" obligations and who can receive 340B-priced drugs thus directly occupies the arena into which Missouri has stepped. S.B. 751's imposition of additional obligations and a separate enforcement scheme is accordingly preempted.

144. S.B. 751 is also conflict preempted because it conflicts with the closed system established by Congress. Congress placed strict limits on the types of entities entitled to 340B pricing and the types of patients that may receive drugs sold at a 340B price. Specifically, Congress provided that only "covered entities" are eligible to receive 340B pricing, and it expressly defined that term to include only fifteen enumerated types of medical facilities. Contract pharmacies are not among the fifteen enumerated covered entities. Congress, therefore, did not intend for retail pharmacies to receive discounted 340B pricing. *See Meese v. Keene*, 481 U.S. 465, 484 (1987) ("It is axiomatic that the statutory definition of [a] term excludes unstated meanings of that term."); *Colautti v. Franklin*, 439 U.S. 379, 392 n.10 (1979) ("[A] definition which declares what a term 'means' . . . excludes any meaning that is not stated.").

145. Congress also expressly prohibited any covered entity from reselling or otherwise transferring a drug bought at the 340B price to anyone other than its patients: "With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or *otherwise transfer* the drug to a person who is not a patient of the entity." 42

U.S.C. § 256b(a)(5)(B) (emphasis added). Several PhRMA members have taken the position in pending litigation that because a retail pharmacy is not a patient of a covered entity, it is prohibited by federal statute from receiving 340B-program drugs. *See, e.g.*, *Eli Lilly & Co.*, No. 1:21-cv-81 (S.D. Ind. May 10, 2021), ECF No. 89 at 29. At a minimum, it is clear that the 340B statute does not expressly allow *covered entities* to transfer drugs to retail pharmacies or require manufacturers to engage in such transfers on behalf of covered entities. Moreover, the federal transfer prohibition also makes clear that the only individuals eligible to receive a covered entity's 340B-priced drugs are patients of the covered entity.

146. S.B. 751, by contrast, purports to *require* drug manufacturers to transfer drugs at 340B prices to pharmacies that maintain a contract with a covered entity—a requirement that can nowhere be found in federal law. It also appears to require manufacturers to do so without regard to whether those drugs will ultimately be dispensed to any patient of a covered entity—without regard to the requirements of federal law.[13]

[13] As discussed, *see supra* at ¶¶ 19-23, the Eighth Circuit previously addressed whether an Arkansas state statute was preempted by 340B. In reaching the determination that it was not, the Eighth Circuit made two erroneous factual findings on appeal of the summary judgment decision that were not supported by the record in that case and were central to its determination: (1) that "the pharmacy becomes an agent of the covered entity" and (2) that "[c]overed entities purchase and maintain title to the 340B-discounted drugs." *McClain*, 95 F.4th at 1142, 1144. The federal government has made clear that, in reality, a principal-agent relationship between covered entities and contract pharmacies does not routinely exist. *See* Hr'g Tr. at 34:10, *AstraZeneca Pharms. LP v. Becerra*, No. 21-cv-27 (D. Del. May 27, 2021), ECF No. 76 (government attorney contending that agency relationship is not a "requirement" for contract pharmacy arrangements); HRSA's Cross-Mot. for Summ. J. at 24 n.4, *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-01686 (D.D.C. Aug. 10, 2021) (no principal-agent relationship requirement for covered entities and contract pharmacies), ECF No. 16-1. And publicly available information indicates that covered entities are not, in fact, maintaining title to 340B-priced drugs when they are provided to contract pharmacies. *See, e.g.*, Dallas County, 340B Contract Pharmacy Services Agreement – ReCept Pharmacy at 5 (Comm'rs Ct.) ("County shall purchase 340B Drugs through a written contract with the Supplier and shall hold title to such drugs from the time the Supplier fills the order from ReCept [(the contract pharmacy)] made on behalf of the County until the time that ReCept takes delivery

147. For those reasons, S.B. 751 is both field and conflict preempted.

CLAIM IV
(Declaratory/Injunctive Relief—Unconstitutional Extraterritorial Regulation)

148. PhRMA re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

149. Under our constitutional framework, states may not directly regulate conduct that takes place wholly in another state. "[A]ll States enjoy equal sovereignty." *Shelby Cnty. v. Holder*, 570 U.S. 529, 535 (2013). "A basic principle of federalism is that each State may make its own reasoned judgment about what conduct is permitted or proscribed within its borders, and each State alone can determine what measure of punishment, if any, to impose on a defendant who acts within its jurisdiction." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003) (citation omitted).

150. The understanding that states may not impose on other states' regulatory powers follows from several Constitutional provisions. States are denied certain powers that a sovereign might ordinarily impose, U.S. Const. art. I, § 10; and required to honor certain rights of other states, U.S. Const. art. IV, §§ 1, 2, 3. Similarly, the Due Process Clause limits a state's ability to regulate conduct occurring wholly outside its borders. *See Watson v. Emps. Liab. Assurance Corp.*, 348 U.S. 66, 70 (1954) (recognizing "the due process principle that a state is without power to exercise

---

of the drugs."), https://dallascounty.civicweb.net/document/22291/340B%20Contract%20Pharmacy%20Services%20Agreement%20-%20ReC.pdf; *see also* Pharmacy Services Agreement Between the County of Monterey and CVS Pharmacy, Inc. at 9, https://monterey.legistar.com/View.ashx?M=F&ID=7977212&GUID=F2A35B03-7A27-42B4-B968-A2C23EBFB315.

Absent those unsupported findings, the invasion of the closed federal field and the conflict with the closed system selected by Congress becomes clear. Congress defined participants in 340B with precision but chose not to include contract pharmacies in the scheme. That choice should be honored and has preemptive effect. *See supra* at ¶¶ 47-48.

'extra territorial jurisdiction,' that is, to regulate and control activities wholly beyond its boundaries"). The Commerce Clause provides that "[t]he Congress shall have Power . . . To regulate Commerce . . . among the several States." U.S. Const. art. I, § 8, cl. 3. Under that clause, states are prohibited from directly "control[ling] commerce occurring wholly outside [its] boundaries." *Healy v. Beer Inst.*, 491 U.S. 324, 335-36 (1989); *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982) (plurality op.). While the Court recently refined the reach of the dormant Commerce Clause, it did not disturb its prior precedent establishing that state laws are unconstitutional where they "directly regulate[] out-of-state transactions by those with no connection to the State." *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 374, 376 n.1 (2023).

151. S.B. 751 is unconstitutional under these principles. S.B. 751 broadly bans all pharmaceutical manufacturers—many of whom have no physical presence in Missouri—from "deny[ing], restrict[ing], or prohibit[ing], either directly or indirectly," a contract pharmacy's "acquisition of a 340B drug." S.B. 751, § 2.

152. Much of the conduct regulated by S.B. 751 will occur wholly beyond Missouri's borders. For example, S.B. 751 will apply to out-of-state transactions between out-of-state manufacturers and out-of-state distributors. It will also apply to out-of-state transactions between out-of-state manufacturers or out-of-state distributors, on one side, and out-of-state covered entities. In sum, S.B. 751 will operate even where the transactions occur out-of-state and involve only out-of-state actors.

153. By directly regulating commerce that occurs entirely outside of its borders, S.B. 751 violates the Constitution's bar on extraterritorial state regulation. *See Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664, 666-71 (4th Cir. 2018) (striking down a Maryland drug-pricing law that "directly regulates the price of transactions that occur outside Maryland[,]" where

the law allowed "Maryland to enforce the Act against parties to a transaction that did not result in a single pill being shipped to Maryland"); *see also Ass'n for Accessible Meds. v. Ellison*, No. 23-cv-2024, 2023 WL 8374586 (D. Minn. Dec. 4, 2023) (concluding that Minnesota statute that barred manufacturers from "impos[ing], or caus[ing] to be imposed, an excessive price increase, whether directly or through a wholesale distributor, pharmacy, or similar intermediary, on the sale of any generic or off-patent drug sold, dispensed, or delivered to any consumer in the state" violated the dormant Commerce Clause).

PRAYER FOR RELIEF

PhRMA respectfully prays that this Court:

a. issue an order and judgment declaring that S.B. 751 is unconstitutional and violates federal law or, in the alternative, an order and judgment that S.B. 751 does not apply in circumstances where manufacturers offer 340B-priced drugs for sale with conditions related to contract pharmacy usage or claims data requirements and covered entities do not accept such offer terms;

b. issue an order and judgment declaring that S.B. 751 does not require PhRMA's members to offer 340B pricing on their covered outpatient drugs to contract pharmacies in Missouri or contract pharmacies located outside of Missouri that fall within the ambit of the statute;

c. enjoin the implementation and enforcement of S.B. 751 against PhRMA's members;

d. enjoin the implementation and enforcement of S.B. 751 as to the sale of PhRMA's members' drugs under 340B;

e. award PhRMA costs and reasonable attorneys' fees, as appropriate; and

f. grant any other relief the Court finds just and appropriate.

Dated: November 22, 2024

Respectfully submitted,

By: */s/ Jean Paul Bradshaw*

Jean Paul Bradshaw II (# 31800)
Jackson R. Hobbs (# 71004)
2345 Grand Blvd. Suite 2200
Kansas City, Missouri 64108-2618
Tel: (816) 460-5507
Fax: (816) 292-2001
jeanpaul.bradshaw@lathropgpm.com
jackson.hobbs@lathropgpm.com

And:

Philip J. Perry*
Andrew D. Prins*
Abid. R. Qureshi*
Latham & Watkins LLP
555 Eleventh Street, NW, Suite 1000
Washington, DC 20004
Tel: (202) 637-2200
Fax: (202) 637-2201
philip.perry@lw.com
andrew.prins@lw.com
abid.qureshi@lw.com

**Admitted pro hac vice*

Counsel for Plaintiff Pharmaceutical Research and Manufacturers of America